ALARA™
INCORPORATED

May 21, 1999

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Director
Center for Devices and Radiological Health
Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fischers Lane
Rm 1061
Rockville, MD 20852

Re: Request for Variance: Source-skin distance § 1020.31 (i) for "DRA-2000"

Note: This request is a modification of and replaces a request of the same topic dated May 10, 1999.

Dear Director,

Alara, Inc. hereby requests a variance from performance standard § 1020.31 (i) concerning source-skin distance for radiographic equipment. The performance standard requires a minimum source-skin distance of 30 cm for portable equipment; Alara requests approval to incorporate a source-skin distance of approximately 15 cm.

Confidentiality
Alara, Inc. confirms that this request and the information herein is releasable.

Description of the Product and its intended use:
Alara is developing the "DRA 2000" (project name) peripheral bone mineral densitometer intended for osteoporosis screening. The DRA 2000 is a self-contained unit which will acquire x-ray images of the non-dominant hand, automatically analyze the images, estimate bone density, and compare the results to normative and age-specific reference population data. These results and comparisons are intended for use as an aid to diagnose osteoporosis or osteopenia and to estimate fracture risk based on the World Health Organization (WHO) criteria. The instrument utilizes storage phosphor image plates and scanning technology. The system contains an electrically controlled x-ray source, and generates printed reports using a commercial, off-the-shelf printer directly attached to the product.

The DRA-2000 is a relatively low-cost instrument intended for use in physicians' offices, clinics, mobile services, and research laboratories for osteoporosis screening and fracture risk estimation. Results provided by the DRA-2000 should be used by the health care provider in conjunction with other information in diagnosing osteoporosis and assessing fracture risk. The DRA 2000 is not intended to be hand-carried during use, or between individual patients. It is, however, expected to be carried to alternative osteoporosis screening locations in between periods of use and is therefore considered portable according to the definition provided in CFR § 1020.30 (b).

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How Compliance with the applicable standard would restrict or be inappropriate for this intended use:
Our product is targeted to primary care physicians, whose offices typically have limited counter space and headroom for counter-top instruments. Since this device is intended for screening, it is also targeted to mobile clinics who conduct screening at remote locations. In order to fully address the requirements of this market, we designed the system to be as compact as possible. Given this requirement for compact size and the technology we use to record and acquire images, our design calls for a focal spot-to-skin distance (FSSD) of approximately 15 cm.

Manner of Deviation
According to CFR 1020.31 (i), a portable x-ray system must have means to limit the FSSD to be no less than 30 cm. Our current design calls for a FSSD of approximately 15 cm.

Alternate Means of Radiation Protection
We understand that the purpose of the minimum FSSD requirement is to avoid exposing the patient to high-intensity, low-energy x rays. In order to meet the spirit of this requirement, our design includes means to ameliorate the effects of the reduced FSSD in terms of patient exposure to low-energy x rays. Our reasoning and approach are described below. For the purpose of this analysis, we define low-energy x-ray photons as those having an energy of 20 keV or less.

To more fully understand this issue, we also considered CFR 1020.30 (m), which specifies that a 60-kV x-ray source should have a minimum half-value layer (HVL) equivalent 1.3 mm of aluminum. We understand that the purpose of this requirement is also to ensure that the patient is not exposed to high-intensity, low-energy x rays by preferentially removing of low-energy x rays via the x-ray attenuation provided by the aluminum.

Our calculations show that for a 60-kV x-ray beam with 0.6 mm equivalent aluminum filtration has a HVL of 1.3 mm of aluminum filtration. For the sake of this discussion, let us say there are 100 arbitrary energy units carried by photons whose energy is 20 keV and below.

By decreasing from 30 cm to 15 cm, according to inverse square law, the intensity of radiation increases by a factor of 4, thus there would be 400 equivalent units of energy at 15 cm FSSD. We would like to reduce the intensity of the low energy x rays by at least a factor of four. This can be accomplished by adding additional filtration to the pre-patient x-ray beam.

Our x-ray source design calls for approximately 3.5 mm equivalent aluminum filtration. This reduces the energy carried by low-energy photons by approximately a factor of 9, well in excess of the factor of 4 required. Note that this level of filtration corresponds to an equivalent HVL of 3 mm aluminum, also well in excess of the required 1.3 mm.

Variance Duration
Alara intends to manufacture all units with this deviation and requests that the deviation remain in effect the maximum allowable time.

Clinical Trial
Pilot-production units will be utilized in a clinical trial. This trial will be conducted with institutional review board (IRB) approval and in compliance with requirements for informed consent.

Environmental Assessment
An environmental impact statement is not required in this petition according to 21 CFR Ch. I § 25.24(e)(3) which categorically excludes "Issuance, amendment, or repeal of a standard for a class II medical device or an electronic product, and issuance of exemptions or variance from such a standard."

Conclusion
In summary, we conclude that our approach to mitigating the effects of a shorter FSSD significantly exceed the beam quality and low energy exposure guidelines outlined in the CFR. Henry Knox (Office of Compliance, Radiological Products) further confirmed this conclusion on April 2, 1999 by stating that a FSSD as small as 10cm would be acceptable on a peripheral-only (but not whole-body) device.

We respectfully request a variance from the 30-cm FSSD requirement for the DRA 2000.

Respectfully,

Diane King
Director of Regulatory Affairs
Alara, Inc.

Certification
I certify that to the best of my knowledge, this petition includes all information relevant to the petition, favorable or not.

Diane King
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